Cancel claims 12, 13 and 15.

REMARKS

Entry of the amendment and reconsideration is respectfully requested. The amendments are in response to points raised in the final Office Action and should lessen the issues on appeal or result in the allowance of the application.

Claims 1-11, 14, and 16-19 are before the Examiner. Claims 7-9, 11 and 18-19 remain withdrawn from consideration.

Claims 1-5, 10 and 14 have been amended to address points raised in the Official Action. Claims 12, 13 and 15 are cancelled.

Rejections under 35 USC 112, Second Paragraph

Claims 1-6, 10 and 12-17 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out distinctly claim containing subject matter which applicant regards as his invention.

The claims have been amended to address certain points raised by the Examiner.

The Examiner is respectfully requested to reconsider certain of the points raised. It is respectfully consider that the use of functional chemical names do not necessarily render the claims indefinite. Please note that the terms "emulsifiers" and "detergents" are not coextensive and therefore each could include compounds not covered by the other. Further, claim 2, as amended, suggests emulsifiers and detergents are present as additional components. Claim 12 is directed to an embodiment where the emulsifier is present to improve the solubility of certain active ingredients.

Also, please note that Cremophor and Cremophor EL are no longer recited in claim 4 and -polyethoxylated castor oil- has been substituted for "Cremophor EL". The chemical nature of Cremophor and Cremophor EL are identified in numerous places within the specification, e.g. passage describing Figure 1 on pages 10 and 11 of the specification.

With regard to "particulate biomaterial", it is thought that when the claim is read in context the meaning is clear. Compounds can exist in a variety of forms and also can be a component of a particulate material.

With regard to "multivitamin", claim 1, as amended now recites active ingredient(s).

Withdrawal of the rejection is respectfully requested.

Rejections under 35 USC 103

Claims 1-6, 10 and 12-17 are rejected under 35 USC 103 as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharrier (5,744,156). Claims 1-6, 10 and 12-17 are rejected under 35 USC 103 as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharrier (5,744,156), in further combination with applicants' statements of prior art. Applicant respectfully traverses both rejections.

Per the Examiner's observation, Claim 1 has been amended to include limitations directed to "differences in latency periods" and the role of the amphiphilic molecule as a causative agent for the side effect treated.

Ko teaches chimeric molecules composed of a first and second polypeptides, both of which inhibit complement activation. The chimeric proteins are taught to reduce inflammation. Conditions mentioned include those associated with ischemia-reperfusion, crash injury, burns, ARDS, autoimmune disorders, etc.. Table 1, referred to by the Examiner, lists potential clinical

targets of the protein chimeras, i.e. targets to try. [1] None is an immediate complement reaction like that disclosed herein. The Table does mention "Drug Allergy".

Accordingly, the teaching of Klaasen (Table1) merely suggest potential applications, e.g. "Allergic Reactions" to drugs, which have characteristics that are distinctly different from the immediate complement reactions of the instant invention.

De Lacharriere teaches the use of a substance P antagonist for the preparation of a pharmaceutical composition for treating skin reddening of a neurological origin. There is no mention of an immediate hypersensitivity reaction associated with complement activation by amphiphilic molecules nor its treatment in the manner claimed.

The teachings of references, taken alone or in combination, are incomplete and thereby fail to suggest the claimed invention.

Further, it is respectfully submitted that the references fail to suggest their combination. There is no problem evident in one for which the other is a solution.

Since a prima facie case has not been established, withdrawal of the rejection is respectfully requested.

[1] The art of pathological conditions associated with complement activation in the field of complement prior to the instant disclosed invention are described in previously submitted Table A. Applicants consulted 44 reviews, research, or textbook articles in the field. Many of these reviews, both before and after 1998 (the Ko, et al patent issued on 22 Dec 98), gave comprehensive listing of pathological conditions associated with complement activation. Each of the pathological conditions mentioned by Ko, et al are included. The first mention of immediate non-IgE hypersensitivity reactions mediated by complement was published by Applicants in Feb, 1998.

Conclusion

Having addressed all of the rejections and objections, allowance of the application is believed to be in order. A notice to this effect is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 210-380 referencing docket no. 38644-170639 (*formerly 378332000900*). However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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BY

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A method for [reducing] treating the symptoms of an immediate hypersensitivity reaction [side effect] caused by an amphiphilic carrier[, and/or active ingredient] comprising administering to a subject a hypersensitivity reducing effective amount of a complement activation inhibitor, [in conjunction with the] active ingredient(s) and the amphiphilic carrier [or a pharmaceutical solvent], wherein said amphiphilic carrier is polyethoxylated oil or a derivatized polyethoxylated oil, and wherein the active ingredient is taxol, paclitaxel, Doxil, althesin, cyclosporin, diazepham, didemnin E, echinomycin, propandid, steroids, teniposide, doxorubicin, daunorubicin, amphoterin B, hemoglobin, polynucleotide or a multivitamin [product].

2. (Amended) The method according to claim 1 wherein said composition further comprises a pharmaceutical solvent and additional emulsifiers or detergent [molecules].

3. (Amended) The method according to claim 2 wherein the pharmaceutical solvent is selected from the group of hydrophilic or hydrophobic solvents.

4. (Amended) The method according to claim 1 wherein the polyethoxylated oil is [Cremophor EL] polyethoxylated castor oil.

5. (Amended) The method according to claim [1] 2 wherein said active ingredient is poorly soluble in water-based solvents [and necessitates the addition of emulsifiers to become soluble].

10. (Amended) The method of claim 1 [comprising] wherein the administration includes: administering to said individual the complement activation inhibitor prior to the administration of said active ingredient.

14. (Amended) The method according to claim 1 wherein said amphiphilic carrier is selected from the group consisting of liposomes, colloidal dispersions, particulate biomaterials[,] and radiocontrast agents[and emulsifiers].